



Consumer Federation of America

April 16, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Performance Standard for *Vibrio Vulnificus*; Request for Comments
Docket No. 98P-0504
64 Fed. Reg. 3300 (January 21, 1999)

The following comments represent the views of the Consumer Federation of America, a non-profit association of more than 250 organizations, representing the interests of over 50 million Americans. CFA works to advance the consumer interest through advocacy and education.

For too many years, raw molluscan shellfish contaminated with the deadly bacterium *Vibrio vulnificus* have exacted a terrible toll on consumers in the United States. Since 1989, the pathogen has killed over 100 people and has sickened many more. The annual death toll has reached as high as 24 (in 1996), and last year another 18 victims died as a result of eating raw shellfish containing *Vibrio vulnificus*. And the pathogen did not take long to strike again this year: on February 3, a Florida man who had consumed raw oysters contaminated with *Vibrio vulnificus* was treated in an emergency room for fever, nausea, vomiting, diarrhea, and abdominal cramps. While this victim did not die as a result of his *Vibrio vulnificus* infection, there is every reason to expect that the pathogen will kill another 10 to 20 consumers before the end of the year, unless immediate, decisive action is taken to improve the safety of raw molluscan shellfish.

The surest way to end this unnecessary loss of life would be for FDA to transform its lax regulations into effective rules that actually prevent dangerously contaminated products from reaching restaurants and stores. We therefore support the

CSPI petition urging FDA to take immediate regulatory action to establish a performance standard for raw molluscan shellfish from waters associated with past *Vibrio vulnificus* infections. The performance standard should require that shellfish processors reduce the pathogen to nondetectable levels in molluscan shellfish intended for raw consumption. With new post-harvest treatment technologies capable of reducing *Vibrio vulnificus* contamination in raw shellfish to nondetectable levels, FDA can act to protect consumers from unnecessary health risks by requiring that the industry produce a significantly safer product, without imposing inordinate costs on the industry.

A Growing Number of American Consumers are at Risk

The need for FDA to take such action is becoming ever more urgent, as the number of people who are especially vulnerable to *Vibrio vulnificus* continues to rise. In addition to those suffering from alcoholism, cancer, and AIDS, a large and growing segment of the population is included in the FDA's list of groups at high risk for serious complications from *Vibrio vulnificus*. For example:

- According to the American Liver Foundation, one out of every 20 Americans will be infected with hepatitis B in their lifetime, and 30 to 40 percent of people with acute hepatitis B show no symptoms.
- About four million Americans are infected with hepatitis C, and the FDA recently announced that an unknown number of Americans given blood transfusions before 1992 may have been exposed to the virus. Many people with hepatitis C also show few or no symptoms for many years.
- According to the American Diabetes Association, 16 million Americans have diabetes. Half of them -- eight million people -- don't know they have it.
- Approximately 30 percent of elderly Americans have low gastric acid.

Thus, with tens of millions of consumers affected, these conditions can no longer be said to be rare ailments in the U.S. population.

The Seafood HACCP Rule and Other Previous Regulatory Efforts Have Not Worked

Despite the mounting death and illness toll from *Vibrio vulnificus*-contaminated raw shellfish, and the growing number of potential victims, the regulatory response to this public-health disaster has been woefully inadequate. There is no evidence to suggest that the refrigeration controls, consumer education efforts, and warning label requirements adopted over the past few years by the harvesting states, in conjunction with the Interstate Shellfish Sanitation Conference (ISSC), have done anything to reduce the death and illness toll from contaminated shellfish. Indeed, careful scrutiny of these feeble measures reveals that even 100 percent compliance would do little to enhance shellfish safety:

- the already weak refrigeration requirements were further eviscerated at last year's ISSC annual meeting, to the point that they now permit raw shellfish routinely to remain unrefrigerated for up to 10 hours during the summer months, a sufficient period of time for *Vibrio vulnificus* concentrations to reach dangerous levels;
- research shows that consumer education in the form of warning signs in retail establishments are wholly inadequate to prevent at-risk individuals from eating raw shellfish; and
- the warning label requirement adopted by the ISSC does not even ensure that the warning will reach consumers, but instead requires warning labels to be affixed to bags of shellfish in wholesale shipments *to retailers*.

Even more disturbing than the states and the ISSC's failure to take appropriate action to protect consumers from shellfish contaminated with *Vibrio vulnificus* is FDA's inability to do so under the recently implemented seafood HACCP rule. In touting the expected economic benefits of that rule, FDA predicted that it would avert anywhere from 12 to 30 annual cases of *Vibrio vulnificus* infection within three years.



Consumer Federation of America

Howard M. Metzenbaum
U.S. Senator (Ret.)
Chairman

FAX

DATE: 04-16-99 *Attn: Jenny Butler*
TO: Hockett's Management Branch (HFA-305)
LOCATION: _____
PHONE: _____ FAX: 301-827-6870
FROM: *Jacqui*
TOTAL NUMBER OF PAGES INCLUDING THIS COVER SHEET: _____

IF YOU HAVE ANY PROBLEMS RECEIVING THIS MESSAGE, PLEASE CALL US
AT: (202) 797-8551 FAX: (202) 797-9093
